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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,843	01/15/2004	Mike A. Clark	PHOE-0188	5090

23377 7590 10/10/2006  
WOODCOCK WASHBURN LLP  
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PHILADELPHIA, PA 19103

EXAMINER
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NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1657

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/757,843	<b>Applicant(s)</b> CLARK, MIKE A.	
	<b>Examiner</b> David M. Naff	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/18/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

A response of 7/19/06 to a restriction requirement of 6/19/06 amended claim 31, added new claims 36-38 dependent on Group III claims, and elected Group III claims 25-34 and 36-38 with traverse.

5 The traverse is persuasive, and Groups I-IV will be examined.

Claims examined on the merits are 23-38, which are all claims in the application.

***Claim Objections***

10 Claim 24 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 23. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

15 The only difference in the methods of claims 23 and 24 is the preamble, and the preambles do not change the method steps claimed. Enhancing circulating half-life in the preamble of claim 23 will be inherent when enhancing tumoricidal activity in the preamble of claim 24, and enhancing tumoricidal activity in claim 24 will be inherent  
20 when enhancing circulating half-life in claim 23. It is suggested claim 23 be deleted.

***Claim Objections***

Claim 35 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 25. When two claims in an application are  
25 duplicates or else are so close in content that they both cover the

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same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The only difference in the methods of the claims is in the  
5 preambles. Treating a tumor as in the preamble of claim 25 will be inherent when treating and inhibiting metastases in the preamble of claim 35, and treating and inhibiting metastases in claim 35 will be inherent when treating a tumor in claim 25. It is suggested claim 35 be deleted.

10 ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

15 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the  
20 invention.

Claims 23 and 24 are confusing by requiring the same methods except for the preamble of claim 23 requiring enhancing circulating half-life, and the preamble of claim 34 requiring enhancing  
25 tumoricidal activity. It is not seen how the same method can enhance circulating half-life without enhancing tumoricidal activity, or the converse. Similarly, it is not seen how the method of claim 25 that has the same steps as the method of claim 35 can treat a tumor and not

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treat and inhibit metastases as required by the method of claim 35, or the converse.

### ***Double Patenting***

5 The nonstatutory double patenting rejection is based on a  
judicially created doctrine grounded in public policy (a policy  
reflected in the statute) so as to prevent the unjustified or improper  
timewise extension of the "right to exclude" granted by a patent and  
to prevent possible harassment by multiple assignees. A nonstatutory  
obviousness-type double patenting rejection is appropriate where the  
10 conflicting claims are not identical, but at least one examined  
application claim is not patentably distinct from the reference  
claim(s) because the examined application claim is either anticipated  
by, or would have been obvious over, the reference claim(s). See,  
e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In*  
15 *re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re*  
*Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*,  
686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164  
USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ  
644 (CCPA 1969).

20 A timely filed terminal disclaimer in compliance with 37 CFR  
1.321(c) or 1.321(d) may be used to overcome an actual or provisional  
rejection based on a nonstatutory double patenting ground provided the  
conflicting application or patent either is shown to be commonly owned  
with this application, or claims an invention made as a result of  
25 activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of  
record may sign a terminal disclaimer. A terminal disclaimer signed by  
the assignee must fully comply with 37 CFR 3.73(b).

30 Claims 23-38 are rejected on the ground of nonstatutory  
obviousness-type double patenting as being unpatentable over claims 1-  
14 of U.S. Patent No. 6,737,259 B1. Although the conflicting claims  
are not identical, they are not patentably distinct from each other  
because the methods of claims 23 and 24 will be inherent when the  
35 compound of the patent claims is prepared, and the methods of claims  
25-38 are obvious uses of the compound of the patent claims since it  
is known to use arginine deiminase for tumor treatment as disclosed in  
the present specification in the background.

***Double Patenting***

Claims 23-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,183,738 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the present claims would have been obvious from the compound and methods of enhancing circulating half-life and enhancing tumoricidal activity required by the patent claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651

DMN  
9/30/06